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# CANCER FACTS

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National Cancer Institute • National Institutes of Health

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## Clinical Trials: Get The Facts About Cancer Prevention Studies

### 1. What are clinical trials and why are they important?

Clinical trials are research studies conducted with people. Cancer prevention trials study ways of reducing the risk, or chance, of developing certain types of cancer. Prevention trials are conducted with healthy people who have not previously had cancer. Prevention trials are also conducted with people who have had cancer and are trying to reduce the chance of either developing a new type of cancer or preventing a reappearance of cancer (recurrence).

There are two kinds of cancer prevention clinical trials. *Action studies* (doing something) focus on finding out whether actions people take, such as exercising more or quitting smoking, can prevent cancer. *Agent studies* (taking something) focus on examining whether taking certain medicines, vitamins, minerals, or food supplements (or a combination of them) can prevent cancer.

Prevention clinical trials are conducted in phases. *Phase I* trials, the first step in testing a prevention agent in people, attempt to identify how best to give the study agent (e.g., by mouth), the dose, and side effects. *Phase II* trials focus on learning whether the agent has an effect in preventing cancer. *Phase III* trials randomly assign people to groups; an intervention group or a control group. The intervention group receives the promising preventive agent, and the control group receives a different agent or a placebo (a look-alike that contains no active ingredient).

Prevention clinical trials are important because through research, scientists hope to determine what steps are effective in preventing cancer or its recurrence.

### 2. Who takes part?

Men and women of all ages, races, and ethnic backgrounds take part in cancer prevention trials.

### 3. What are the possible pros and cons of taking part?

#### ***Pros***

- C Clinical trials are designed to answer important scientific questions and help researchers learn more about cancer prevention.
- C People in the trial get regular and careful medical attention, so some health problems may be found early.
- C If the study agent is effective in preventing cancer, some people in the trial are likely to benefit, and knowledge about the study agent may be used to help other people as well.

#### ***Cons***

- C The side effects and risks may not be understood completely.
- C The method being tested may not prevent cancer.
- C Not everyone will receive the study agent.
- C People cannot choose the prevention approach they receive.

### 4. What is informed consent?

Informed consent means that people are given information about the trial to help them make a decision about whether to participate. They need to understand what is involved, including details about the prevention approach, tests, and the possible risks and benefits before agreeing to take part in the trial. After they have discussed all aspects of the study, they receive an informed consent form to read. The form explains the study in detail. If a person agrees to take part in the trial, they sign the form. If new benefits, risks, or side effects are discovered during the trial, the researcher informs participants. Participants are always free to leave the study if they choose.

### 5. How are people who take part in clinical trials protected?

- C Clinical trials are carefully reviewed to be sure the study is reasonably safe and ethical before anyone participates.
- C Those who take part are monitored very closely during and after the trial.
- C Each study site has an Institutional Review Board that reviews the trial for patient safety.

## **Before deciding to enter a clinical trial, people should get the facts.**

Here are some questions to ask your doctor or nurse:

### **The Study**

- C      What is the purpose of the study?
- C      Has this action or agent been studied before? Why do doctors think it might prevent cancer?

### **Possible Risks and Benefits**

- C      What are the possible risks, side effects, and benefits of taking part in this study?
- C      How long will they last? How likely are they?

### **Patient Care During the Study**

- C      What kind of tests can I expect? How will they affect me?
- C      How long will the study last?

### **Personal Issues**

- C      Will my medical records be kept confidential?
- C      How will the study affect my daily life?
- C      Will insurance cover the costs of tests, medicine, supplements, vitamins, or minerals?

For more information about cancer prevention clinical trials, talk to your doctor, call the National Cancer Institute's Cancer Information Service at 1-800-4-CANCER (1-800-422-6237), or visit the National Cancer Institute's clinical trials website at <http://cancertrials.nci.nih.gov> via the Internet.

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## **Sources of National Cancer Institute Information**

### **Cancer Information Service**

Toll-free: 1-800-4-CANCER (1-800-422-6237)  
TTY (for deaf and hard of hearing callers): 1-800-332-8615

### **NCI Online**

#### ***Internet***

Use <http://www.cancer.gov> to reach NCI's Web site.

***CancerMail Service***

To obtain a contents list, send e-mail to [cancermail@icicc.nci.nih.gov](mailto:cancermail@icicc.nci.nih.gov) with the word "help" in the body of the message.

**CancerFax®** fax on demand service

Dial 301-402-5874 and listen to recorded instructions.

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